

EXHIBIT 3

1 IN THE UNITED STATES DISTRICT COURT.
2 FOR THE DISTRICT OF NEW JERSEY
Civil No. 00-02931 (JCL)

3 WARNER-LAMBERT COMPANY

Transcript of
Proceedings

4
5 V.

6 PUREPAC PHARMACEUTICAL COMPANY,
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Newark, New Jersey
September 24, 2004

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10 B E F O R E: HONORABLE JOHN C. LIFLAND,
11 UNITED STATES DISTRICT JUDGE

12 A P P E A R A N C E S:

13 DRINKER, BIDDLE & REATH
14 BY: JOHN J. FRANCIS, JR., ESQ.
AND
15 FITZPATRICK, CELLA, HARPER & SCINTO
BY: HUGH C. BARRETT, ESQ.
16 AND: ROBERT L. BAECHTOLD, ESQ.
For Pfizer and Warner-Lambert.

17 FOR THE DEFENDANTS:

18 LITE, DE PALMA, GREENBERG & RIVAS
19 BY: ALLYN Z. LITE, ESQ.
AND
KENYON & KENYON
20 BY: THOMAS J. MELORO, ESQ.
AND: STEVEN J. LEE, ESQ.
21 For Teva Pharmaceuticals, Generic Defendants.

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 8 FOR Purepac Pharmaceutical Co. And Faulding, Inc.

9 SCHIFF HARDIN
 10 BY: JOHN C. MARTIN, ESQ. (IL BAR)
 11 For Geneva.

12 MATHEWS, COLLINS, SHEPHERD & MC KAY
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 14 For Ranbaxy.

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 17 AND
 18 DONALD HOROWITZ, ESQ.
 19 For Eon Labs.

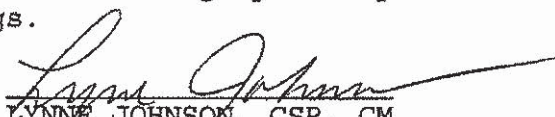
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 Pursuant to Section 753 Title 28 United States

Code, the following transcript is certified to be an accurate
 record as taken stenographically in the above-entitled
 proceedings.


 LYNNE JOHNSON, CSR, CM
 Official Court Reporter

1 THE COURT: Welcome to the fifth floor.

2 A scheduling note. A request was made yesterday
3 that we sit no later than two o'clock today for the
4 observances of some, and that is fine. In fact, just five
5 minutes ago I found out that I have to break at 1:30 so I can
6 get to see a doctor.

7 So I hope that won't inconvenience anybody to break
8 a half an hour earlier than was requested.

9 I have set aside Monday for a continuation, if
10 necessary. And we will see.

11 The motion for a preliminary injunction as made by
12 Warner-Lambert is based upon the information it has received
13 as to an impending launch of Purepac's formulation, which
14 Warner-Lambert feels violates the '482 patent.

15 I have received extensive briefing from both sides.
16 There has not been time for the normal three steps of
17 briefing in situations like this. And accordingly, I am
18 going to ask Warner-Lambert to speak to the subject of best
19 mode which was -- to which Purepac has devoted 22 pages in
20 its brief. I think that is, that makes sense to me.

21 We will see where that takes us.

22 Before anybody says anything, there have been
23 inquiries as to whether the courtroom should be closed for
24 some part of the proceedings.

25 I asked Mr. Basilone to reach out to counsel and

1 get their views on that. My understanding is counsels'
2 response has been "maybe." Perhaps I should pursue that
3 first before I pursue anything else.

4 Who wants to speak on that? Mr. Francis.

5 MR. FRANCIS: Warner-Lambert would just as soon it
6 is open. We have no objection one way or the other.

7 MR. HAUG: Good morning. Ed Haug for the defendant
8 Purepac.

9 If I can, on behalf of Teva, they can speak for
10 themselves, we don't have a problem with it being open until
11 we get to the financial evidence in the case. We prefer it
12 that way which I suspect will come off through the
13 irreparable harm discussion and there is a host of
14 highly proprietary confidential financial information and
15 contractual dealings that have all been filed under seal.
16 And we would very much like not to have to disclose those
17 publicly.

18 The suggestion I think I had made yesterday to the
19 clerk is that perhaps we, one way of possibly dealing with
20 that, your Honor, is maybe we could have one section of the
21 hearing that might be -- where we could seal the courtroom in
22 some way, just that portion if we get into that.

23 THE COURT: All right. You are talking about
24 Purepac's financial information?

25 MR. HAUG: Correct, your Honor.

1 THE COURT: I am sorry to be distracted here. I am
2 looking for the document that was just handed to me five
3 minutes ago from Mr. Lite. It is here some place. I haven't
4 had a chance to read it.

5 MR. LITE: Mr. Basilone, here is an extra copy.

6 THE COURT: Thank you, Mr. Lite.

7 (Pause).

8 THE COURT: All right. I have reviewed the
9 declaration of John W. Blank, III, submitted by Mr. Lite.

10 MR. LITE: Your Honor, if I may, that is being
11 filed under seal as well, and however the Court chooses to
12 treat Purepac's financial information, we would ask that on
13 behalf of Teva that this information be treated the same way.

14 If your Honor would close the courtroom, we
15 certainly think that that would be appropriate. If your
16 Honor thinks that maybe something other than closing the
17 courtroom, or at least outside counsel, we could be heard at
18 sidebar when these issues come up, I think that might be
19 appropriate, however your Honor wishes.

20 THE COURT: I will certainly hear counsel before I
21 close the courtroom.

22 The plaintiff has express a view that the courtroom
23 not be closed for any part of these proceedings. My
24 preliminary observation about Mr. Blanke's declaration is
25 that he talks about what he heard at a sales meeting,

1 essentially a convention. And that is a little different
2 than Purepac's financial information.

3 MR. LITE: Your Honor, the other part that Mr.
4 Blanke's declaration that talks about the intentions of Teva,
5 in light of what happened, in light of what Mr. Blanke has
6 said in his declaration, about Teva's intentions, depending
7 on what happens at the hearing today, is information that I
8 would like, if possible the Court would keep under seal until
9 such time as a determination is made by the Court that it can
10 be made public.

11 THE COURT: All right. I have indicated what I
12 would like to hear about first. I can see that I am going to
13 be provided with a Power Point presentation by somebody.
14 Does that relate to best mode?

15 MR. HAUG: Not from my point, your Honor, no.

16 THE COURT: Okay. Then save some electricity if
17 you want. Turn it off. Or whatever you would like is fine
18 with me. Okay.

19 All right. Who wants to speak for Warner-Lambert
20 in response to the best mode presentation that came with
21 Purepac's proof?

22 MR. BARRETT: Your Honor, Mr. Barrett from
23 Fitzpatrick, Cella. I will speak to that issue. The Power
24 Point presentation is not mine, so I don't know how to turn
25 it off.

1 THE COURT: Somebody has got to confess to it.

2 Talk from the lectern, please, to help the
3 reporter.

4 Are the microphones at the desks working well? If
5 so, I don't have any objection to speaking from the desk, if
6 you cut off to the microphone. But the final arbiter of that
7 is going to be the reporter.

8 (Off-the-record discussion).

9 THE COURT: Just to set the stage, if it needs to
10 be set. At pages 15 to 37 of its brief, within the overall
11 ambit of its presentation on success on the merits, Purepac
12 argues that there is a substantial question of validity based
13 upon the failure to disclose the best mode, the
14 specification.

15 I would ask Mr. Barrett on behalf of Warner-Lambert
16 to respond to that. That was not part of our discussion a
17 month ago with respect to Ivax's launch.

18 MR. BARRETT: Actually, your Honor, as I understand
19 the brief, it goes all the way up to page 42. And I must
20 say, it came as much of a shock to Warner-Lambert to find
21 that their opposition brief was devoted to this subject, as I
22 am sure it has come to the Court, because the Court hasn't
23 heard about this subject before.

24 It has not been the subject of a summary judgment
25 motion. It has not specifically been raised by Purepac as a

1 defense except to mention some aspects of it in one or more
2 of their expert reports. And I am sure that it is here
3 because Purepac's believes that the more they say here the
4 more they are going to make the entire issue of this
5 preliminary injunction difficult to deal with at this time.

6 There is another 30 pages the Court has to get
7 through and find that we show no substantial merit to their
8 defense.

9 But like most of Purepac's other defenses, your
10 Honor, and with all respect to Purepac, there is as much
11 smoke and mirrors in this best mode defense as there is in
12 their chloride claim construction defense or their chloride
13 noninfringement defense, or their adjuvant titanium oxide
14 defense. They all follow the same mold, which is, your
15 Honor, it is a mold that is, that lends itself to smoke and
16 mirrors because of a chemical nature of this case. Chemistry
17 can be very confusing. The nomenclature itself is
18 incomprehensible. So it is easy to go around and make all of
19 these arguments and then to expect your Honor to try to
20 figure them out is a formidable expectation.

21 Let me tell your Honor a little bit about best
22 mode. I don't know if it is a patent issue that you have
23 dealt with in prior cases. It is another one of these
24 so-called Section 112 defenses. It is not a validity defense
25 based on prior art. It is a validity defense based on the

1 patentee's failure to put into the specifics of the patent
2 the things that he has meant to include there to deserve the
3 awarding of this grant of the exclusivity on the invention
4 for the period of time that a patent runs.

5 You know about Section 112 defenses because Purepac
6 has raised two other validity attacks. Purepac has not
7 raised, as we mentioned, any validity attacks based upon
8 prior art which is the standard of validity attack on a
9 patent. They have raised two Section 112 validity attacks in
10 their summary judgment motions.

11 As I said before, and I will say it again, although
12 Mr. Mentlick disagreed with me, Section 112 invalidity
13 attacks are not favored. They are very technical. There are
14 not many cases where a patent has been held to be invalid for
15 one reason or another based on Section 112. But it is a
16 requirement of the patent statute that the patent entity has
17 to include certain things in its specification.

18 As you know from the other motion, and defenses
19 that they have raised before, he needs to meet, he needs to
20 provide a written description of his invention. She needs to
21 be sure that his specification is not, and the description of
22 the invention is not so indefinite that one skilled in the
23 art is not able to ascertain the scope of the claims.

24 But the third requirement from Section 112, the
25 best mode, is perhaps the one that is most misunderstood, and

1 the one that is perhaps the most difficult to get a grip on
2 in some cases. But certainly not in this case, as I will
3 show your Honor.

4 I do want to point out to you that there, as I
5 understand it, there have only been in the history of the
6 Federal Circuit, in the 20 years now of the Federal Circuit,
7 they have only held seven patents invalid on the basis of
8 best mode defense. It is not, and there have been many,
9 many, many more attacks on the patent for best mode defense.
10 But there has only been seven, and these seven cases where
11 best modes have been used as a method to invalidate the
12 patent are all set out in the case that Purepac cites in the
13 case, this Beyer case, which Beyer did end up finding there
14 was no best mode violation even in that case.

15 But they are all set out in there, your Honor could
16 take a look at that and look at the unique circumstances. It
17 certainly is a defense that requires a very factual
18 case-by-case basis, no general principles that are really
19 defining, except that the idea is that the inventor needs to
20 put into his invention the so-called best mode.

21 What does that mean? That means that the inventor
22 cannot hide the ball from the public once the patent issues.
23 For example, if he develops a process for making a chemical,
24 and he claims that process, and that is the invention. And
25 it has several steps. But he discovered in his laboratory

1 that in step three of that process, that step three really
2 only worked if he put in this magic extra chemical, he put in
3 some extra gobbledygook and then claimed that process really
4 worked, really worked. But he doesn't mention that in his
5 patent. He just mentions, "Run step three." And then when
6 people skilled in the art try to follow the steps of the
7 patent they have a problem getting through the process
8 because step three doesn't work very well and they have to go
9 through all kinds of experimentation at which time they may
10 or may not find that particular secret ingredient he threw in
11 to make the process work.

12 That is something that the patent law frowns on.
13 You don't want to hide the ball in terms of specifically what
14 you are claiming is your invention. That is where the best
15 mode defense, the best mode requirement has come from. And
16 it certainly does make sense. It makes sense that certain
17 inventions, it is important to be sure that those critical
18 elements that make it necessary, that are necessary -- that
19 are necessary for practicing the invention are disclosed in
20 the patent. Absolutely something Warner-Lambert agrees with
21 100 percent. But that is certainly not the case here. It is
22 not the case, and it is very difficult to get through these
23 30 pages of the brief and try to figure out why it is not the
24 case.

25 By I ask the Court as I go through this very

1 quickly just to keep in mind one thing, and that is that the
2 basic attack that we are having on the patent on the best
3 mode defense, on their best mode defense, is that -- let me
4 go back a step.

5 As your Honor is probably aware by this point in
6 time, our claim has two aspects to it. There is the chloride
7 aspect and there is this adjuvant aspect. And the adjuvant
8 aspect relates to the fact that certain adjuvants which are
9 these ingredients you put into the drug before you can mix
10 them into a tablet or capsule, you can't just put the
11 straight drug in there. It doesn't work that way. You have
12 to mix it with a filler or something.

13 These ingredients unpredictably have an effect on
14 the lifetime formation. It is not something Warner-Lambert
15 expected. They discovered to make a reasonable formulation
16 you needed to be aware of this problem. You needed to be
17 aware certain excipients might be more of a problem in
18 forming lactam than other ones. If you weren't aware of that
19 and you made a formulation and tested one and found it was
20 unstable lactam formation over a short period of time you
21 wouldn't know where to look for the solution to the problem.
22 You wouldn't know whether, of course if you didn't have the
23 '482 patent in front of you, you wouldn't know it was a
24 hydrochloric acid content. You wouldn't know the excipients
25 were causing the problem. That is not to say it is not a

1 standard skill in the art to realize that certain excipients
2 are better than others in drug formulations. That was none.

3 But in this case, this unpredictability of which
4 excipients can really have some major effect on lactate
5 formation wasn't known. The patent, the teaching and
6 invention that is embodied in this section of the '482
7 patent, the adjuvant portion, is that it is teaching someone
8 skilled in the art how to make a proper Gabapentin
9 formulation, how to take one or more of the millions of
10 excipients, potential excipients that are out there to put in
11 a drug and how to pick and choose the ones that work best for
12 your formulation, what your company wants to do, what kind of
13 problem they want to make, how big they want to make it, what
14 kinds of machines they have, do they need more of this
15 excipient for lubrication on their capsule-filling machine or
16 they need more filler because they are using this capsule.

17 Every formulation is different, but the idea is
18 this patent teaches you how to make a formulation that is
19 stable by looking at the excipients and realizing that
20 certain excipients have a greater effect, negative effect on
21 lactam formulation than others and taking that into account
22 and possibly -- not possibly, but probably, tinkering with
23 the formulation, changing amounts of excipients, changing
24 excipients to come up with a formulation that satisfies your
25 need for a product that is stable enough to file with the

1 FDA, that is basically what I would believe is a teaching
2 of what that adjuvant portion of the claim is getting to.

3 Now, why do I talk about that in connection with
4 best mode? Because what defendants say is that in the course
5 of making their invention, the Warner-Lambert scientist in
6 Godecke Germany developed two, a formulation that they called
7 their preferred formulation, their so-called market image
8 formulation. And that this preferred formulation is the one
9 that Warner-Lambert knew worked. I guess the assumption, or
10 the inference is that other formulations didn't work. But
11 this formulation worked. And it contained these three
12 mysterious ingredients, corn starch, lactose and talc.

13 And we knew this, we knew this, and we didn't tell
14 the public in our invention, in power patent, we wanted to
15 hide the real formulation that worked. This so-called image
16 formulation, and they demonstrate that it was the formulation
17 that was developed originally at Godecke early on and that
18 that formulation carried through in its formulation that
19 Warner-Lambert is using in its capsule product today. And
20 that is true.

21 What defendants don't say is that -- One more
22 thing. What defendants suggest is that no other formulation
23 works. And you got to know this formulation. And if you
24 didn't have the teaching in the patent, how would you know
25 what formulation would work. And you would have to go

1 through incredible experimentation to come up with this
2 formulation, and that in fact, all the ANDAs have been filed,
3 everybody uses the same three components, lactose, corn
4 starch, and talc formulation.

5 The real facts are so far from that, your Honor.
6 First of all, the preferred formulation that they referred to
7 that Warner-Lambert selected was the one that Warner-Lambert
8 decided fit their needs. It fit their bill. First of all,
9 as Dr. Gebhart, one of the inventors, he was the inventor on
10 the formulation side, testified in deposition, Purepac hasn't
11 included this in their brief, he testified that the reason
12 they started with corn starch, lactose and talc is because
13 those are three of the most common ingredients in drug
14 formulations today, at the time he developed the invention
15 and they were certainly by far the most common ingredients
16 in drug formulations being developed at Godecke at that
17 time and they had tons of corn starch, lactose and talc in
18 their laboratory and a lot of experience with it so they
19 started with that one. And sure enough, that worked. That
20 worked.

21 It did not provide the kinds of instability that
22 some of the other formulations they did make using other
23 ingredients, such as magnesium stearate, tended to come some
24 lactam formation. That is what our patent was about,
25 teaching people that certain ingredients have more of an

1 effect than others.

2 So it wasn't a secret, necessarily the only
3 formulation that worked. It was the formulation we selected
4 because that worked, whether that worked with our experience,
5 our machines, our capsules, that is what worked, and that is
6 not to make my point short, that is not what the best mode is
7 about. This was not a matter of we were hiding the best mode
8 of our invention. This was just one formulation.

9 The suggestion that this is the only formulation
10 that works is just -- is ridiculous, your Honor.

11 First of all, even Purepac is forced to admit that
12 they started off using our three-component formulation. You
13 asked how did they know how to use our three-component
14 formulation.

15 Well, I suggest that probably it was the most
16 common formulation in their laboratory also. But they say
17 that the reason they knew to use that three-component
18 formulation was that they had read our label which came out
19 in 1994 when our drug came on the market. This is the FDA
20 label. In that FDA label that comes in your package of
21 Neurontin you have to list the ingredients in your product.
22 That label indeed lists lactose, corn starch and talc. They
23 say that is how they knew to use those three ingredients and
24 thank God they had that advanced warning how to do it. That
25 we failed to give them a patent. Best mode.